CHAPTER 1
PURPOSE AND NEED

1.1 BACKGROUND

Rocky Mountain Laboratories' (RML) mission is to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Following events of September 11, 2001, and the anthrax attacks soon after, the public is aware of the potential for exposure of the civilian population to bioterrorism. President Bush and Congress directed the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into development of safe and effective measures to protect the public. These goals are commensurate with past and current research by NIAID. Research is needed to develop safe vaccines and drugs to prevent or cure infectious diseases. In response to this need for research directed at protecting public health, Congress authorized $66.5 million to NIAID for construction of a biosafety laboratory and related infrastructure (Public Law 107-117, January 10, 2002). NIAID has also developed a *Strategic Plan for Biodefense Research* and a research agenda for priority (Category A) biological agents, which is included as **Appendix A** (USDHHS 2000a, b).

A lack of available and adequate facilities is a major impediment to the study of organisms. As a result, many important pathogens have received little attention recently, and many have not been examined using the tools of modern science. This research deficit becomes most apparent now when there has never been a greater demand for information on the pathogens and host responses to them. Information from basic research studies is critical for development of effective vaccines and therapies to combat infectious diseases. Such products can be developed only through understanding the basic biology of disease-causing agents. Cutting-edge discoveries in infectious disease research have resulted from NIAID programs. It is proposed to enhance the capability of the Institute to carry out basic research on important pathogens in this proposed facility. These enhanced capabilities, once in place, would have an additional benefit to the American public in that they would strengthen the nation's ability to respond to outbreaks of naturally occurring diseases. Recent outbreaks of SARS and West Nile Fever underscore the need to have an extensive and flexible infrastructure to support infectious disease research to meet the challenge of emerging diseases.

NIAID has a history of research that has had global impacts on public health improvement. This research capability allows NIAID to address unknown, future health threats associated with emerging and re-emerging infectious disease. NIAID is comprised of both intramural and extramural research areas. The Division of Intramural Research (DIR) and the Vaccine Research Center conduct intramural research. The DIR is located in laboratories on the main NIH campus in Bethesda, Maryland; the Twinbrook facilities in Rockville, Maryland; and the Rocky Mountain Laboratories in Hamilton, Montana. DIR conducts research in virology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics, and supports clinical, patient-centered research in allergy, immunology, and infectious diseases at National Institutes of Health's (NIH) Clinical Center (NIAID 2002a). NIAID supports extramural research, done by non-federal scientists in universities, medical schools, hospitals and research institutions.

NIAID is one of 27 institutes or centers of NIH. NIH is one of 12 agencies of the U.S. Department of Health and Human Services.

RML does not and will not work on or develop biological weapons, as this is forbidden by a national security directive and international law. President Nixon, in 1969, agreed to a National Security Decision Memorandum (35), which renounced use of lethal methods of bacteriological/biological warfare and ordered destruction of all stockpiled agents. The U.S. signed the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, which became effective March 26, 1975 (signed by President Ford and ratified by Congress), which remains in effect

today. The U.S. government maintains the position that there is no justification, including retaliation, for offensive biological weapons research or use.

As part of the expanded research program, NIH is proposing to construct an Integrated Research Facility and complete infrastructure upgrades to existing facilities at the RML campus in Hamilton (**Figure 1-1**). In the U.S., facilities to conduct research with pathogenic material at the highest level of containment are limited to Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas.

Public participants have expressed concern over installation of the proposed Integrated Research Facility and potential risks of biological and infectious agents to be studied. This Final Environmental Impact Statement (FEIS) analyzes potential impacts associated with the proposed Integrated Research Facility as required by the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. § 4321 *et seq.*), and U.S. Department of Health and Human Services General Administration Manual Part 30: Environmental Protection. This document follows the Council on Environmental Quality's regulations for implementing procedural provisions of NEPA (40 CFR Parts 1500-1508).

1.1.1 Organization of the Document

Chapter 1 – Purpose and Need. This chapter explains the purpose and need for the Proposed Action. It also includes a summary of public comment and how issues raised during public scoping were used.

Chapter 2 – Proposed Action and Alternatives. This chapter discusses in more detail alternatives considered in the EIS and compares them.

Chapter 3 – Affected Environment. This chapter explains the current condition of resources that may be affected by the Proposed Action. Resources that would not be affected are identified and rationale provided as to why they will not be discussed further.

Chapter 4 - Environmental Consequences. This chapter discloses potential effects of alternatives, including direct, indirect, and cumulative effects.

Chapter 5 - Response to Comments. This chapter contains a copy of all comments received on the SDEIS along with NIH's response to substantive comments.

Appendix A - Strategic Plan for Biodefense Research.

Appendix B - Characteristics of Diseases Studied at RML.

Appendix C - Transportation of Agents.

Appendix D - Review of Biocontainment Laboratory Safety Record.

Appendix E - Standard Operating Procedures for a BSL-4 Facility.

1.1.2 Required Disclosures

In accordance with section 40 CFR 1502.16 (Regulations Implementing the Procedural Provisions of NEPA), the following list details the required disclosures and where they can be found:

- Direct and indirect effects and their significance (Chapter 4);
- Potential conflicts between the Proposed Action and objectives of federal, state, and local land use plans, policies, and controls (Chapter 1);
- Potential environmental effects of alternatives (Chapter 4);
- Energy requirements and conservation potential and mitigation measures (Chapter 2 – Proposed Action);
- Natural and depletable resource requirements, conservation potential, and mitigation measures (Chapter 2 – Proposed Action);
- Urban quality, historic and cultural resources, and design of the built environment (Chapter 3 and Chapter 4 – Historic Resources); and
- Means to mitigate adverse environmental impacts (Chapter 4).

1.2 HISTORY OF ROCKY MOUNTAIN LABORATORIES

RML is located in Hamilton, Montana, approximately 50 miles south of Missoula, in Ravalli County. Hamilton has a population of approximately 3,700 and is located in the center of western Montana's Bitterroot Valley. RML is located east of the Bitterroot River in the southwest portion of Hamilton (**Figure 1-1**).

Infectious diseases are the second leading cause of death worldwide (WHO 2000) and rank third in the United States (Armstrong *et al.* 1999). NIAID, through work at the RML facility, "conducts and supports research that strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten millions of human lives" (USDHHS 2000a). NIAID has a history of research that has had global impacts on public health improvement, which allows it to address unknown, future health threats associated with emerging and re-emerging infectious disease.

RML began in 1902 as a camp that served as a research laboratory. The researchers found that ticks transmitted Rocky Mountain spotted fever. During the 1920s, ticks were ground up to make a vaccine for this disease at RML.

After successful work with spotted fever, RML expanded its facilities and programs in the 1930s and 1940s to work on other insect-borne diseases, including yellow fever and spirochetal relapsing fevers. In the 1940s, scientists made vaccines (in buildings that are part of RML's current complex) that protected troops against typhus and yellow fever during World War II.

In 1948, RML and the Biologics Control Laboratory joined the Division of Infectious Diseases of the NIH to form the National Microbiological Institute. Six years later, Congress gave the institute its present name, NIAID, to reflect inclusion of allergy and immunology research.

In 1979, the laboratory was renamed Rocky Mountain Laboratories because it consisted of multiple laboratories and branches. The current organizational structure consists of the Laboratory of Persistent Viral Diseases, Laboratory of Human Bacterial Pathogenesis, Laboratory of Intracellular Parasites, Rocky Mountain Veterinary Branch, and the Administrative and Facilities Management Section (USDHHS 2002a).

In 1982, the agent that causes Lyme disease, also transmitted by ticks, was identified at RML. Today, scientists at RML are investigating infectious diseases including Rocky Mountain spotted fever, chlamydia, HIV/AIDS, Q fever, tuberculosis, plague, Lyme disease, salmonella (typhoid fever), and transmissible spongiform encephalopathies (e.g., sheep scrapie and mad-cow disease).

1.3 ELEMENTS OF BIOSAFETY CONTAINMENT

The three elements of containment in biosafety laboratories are laboratory practice and technique, safety equipment, and facility design. The pathogen, health hazard, and research purpose (e.g., tissue culture, vaccine production) determine the elements of containment necessary (USDHHS 1999). Biosafety levels are combinations of these elements (**Table 1-1**).

While certain biological agents may require a given biosafety level (e.g., syphilis is BSL-2 for all procedures), the recommended biosafety level may vary by agent and type of research. An example using hantavirus helps to illustrate this point.

Hantaviruses are Category C biological agents according to U.S. Department of Health and Human Services (USDHHS 1998). Category C agents are emerging pathogens that could be engineered for mass dissemination in the future because they are available, easy to produce and disseminate, and have potential for high mortality rates and major health impacts. Hantavirus pulmonary syndrome is an emerging disease. According to biosafety standards (USDHHS 1999), BSL-2 practices and procedures are recommended for laboratory handling of sera with potential infections of hantavirus pulmonary syndrome. Use of a certified biological safety cabinet (BSC) is recommended for handling human body fluids when potential exists for spillage or aerosol. Potentially infected tissue samples are handled in BSL-2 facilities following BSL-3 practices and procedures. Cell-culture virus propagation is carried out in a BSL-3 facility following BSL-3 practices and procedures. Preparation and handling of viral concentrates is performed in BSL-4 containment facilities. Therefore, appropriate biosafety levels and the agent and type of research determine which procedures are to be used. Additional operational procedures may be implemented based on experience.

1.4 PURPOSE AND NEED FOR ACTION

The purpose for the Proposed Action (described in detail beginning on page 2-1) is to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents. Because of its traditional strengths in the area of infectious disease research and the federal funding parameters associated with NIAID's intramural laboratory program, the Integrated Research Facility is proposed to be located at RML in Hamilton, Montana.

To protect citizens of the U.S., the public health system and primary healthcare providers must be prepared to address these various biological

Table 1-1.
Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench-top sink required
2	Associated with human disease, hazards are percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers are Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE are laboratory coats, gloves, and face protection as needed	BSL-1 plus: Autoclave available Directional airflow into laboratory
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	Primary barriers are Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPE are protective lab clothing, gloves, respiratory protection as needed, and solid front gowns	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	<u>Cabinet Laboratory</u> All procedures conducted in Class III BSC; workers not in full-body, air-supplied, positive pressure suit <u>Suit Laboratory</u> Procedures conducted in suit lab area in combination with Class I or Class II BSCs; Workers in full-body, air-supplied, positive pressure suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

BSL = Biosafety Level
BSC = Biological Safety Cabinet
PPE = Personal Protective Equipment.
Source: USDHHS 1999.

agents, including rarely seen pathogens. Research plays a major role in developing techniques for identifying and characterizing biological agents. Also, several of the "critical biological agents" identified in the Centers for Disease Control and Prevention's (CDC) strategic plan are listed as priority emerging or re-emerging diseases in CDC's strategy for preventing emerging infectious diseases (USDHHS 1998).

The goal of successful preparation for the threat of diseases depends in large measure on availability of effective diagnostic tests, vaccines, and therapeutic drugs. Information from basic research studies is critical for development of effective vaccines and therapies to strengthen the response to outbreaks. Effective vaccines and therapies can be developed only through understanding the basic biology of disease-causing agents.

The President's budget for 2003 devotes funds to NIAID for basic and applied research, including funds designated specifically for construction of intramural facilities.

NIAID has developed a research agenda for Category A agents (USDHHS 2002b). Category A agents are easily transmitted from person to person, have high mortality rates, may have major public health impacts, might cause public panic and social disruption, and require special action for public health preparedness. The research agenda emphasizes the following five interrelated areas:

- Basic biology and disease-causing mechanisms;
- Host immune response;
- New and improved vaccines;
- New and improved treatments against new and drug-resistant agents; and
- New techniques for rapidly and accurately identifying the disease agent.

In order to conduct necessary research to gain an understanding of pathogen and host response, specialized high-containment laboratories are required. Building upon available expertise is required for a response in a timely fashion. The need for the Project (construction of the proposed Integrated Research Facility at RML) is based on the following aspects of the current facility at RML:

- RML is renowned for expertise in research on infectious microbes;
- Researchers at RML provide a core of unparalleled scientific knowledge uniquely qualified to develop strategies and products to counter emerging and re-emerging diseases;
- RML currently has BSL-2 and BSL-3 laboratories;
- Existing infrastructure at RML can efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through basic research as well as detection, investigation, control, and prevention of diseases.

Emergence of new diseases (e.g., HIV/AIDS, hantavirus pulmonary syndrome, severe acute respiratory syndrome (SARS), West Nile fever) and re-emergence of drug-resistant pathogens (e.g., tuberculosis, malaria, *Staphylococci aureus*) are reminders that infectious diseases remain dominant features of national and international public health (USDHHS 1998; Fauci 2001). Societal, technological, and environmental factors (e.g., population growth, poverty, ease of travel, alteration of habitats) facilitate occurrence and spread of disease. A critical need exists for continued research, not only on new diseases, but also on old and familiar ones.

A lack of available and adequate facilities is a major reason that study of these organisms has received little attention in the recent past. There has never been a greater demand for basic information on pathogens and host responses for development of effective vaccines and therapies. Such information can be developed only through understanding of the basic biology of disease-causing agents in laboratories designed with the highest safety precautions (BSL-4).

1.5 SCOPE

The scope of the Project is established by the purpose and need and by U.S. Department of Health and Human Services (USDHHS) procedures and authority. The scope (40 CFR 1508.25) consists of the range of actions, alternatives, environmental issues, and impacts to be considered and discussed in the EIS.

1.5.1 Impacts

Regulations contained in 40 CFR 1508.25[c] require analysis of direct, indirect, and cumulative impacts. Direct impacts are caused by the action and occur at the same time and place. Indirect impacts are caused by the action and occur later in time or farther removed in distance, but they are still reasonably foreseeable. Cumulative impacts result from incremental impact of the action when added to other past, present, and reasonably foreseeable future actions.

1.5.2 Alternatives

In determining the scope of analysis, NIH must consider three types of alternatives (40 CFR 1508.25[b]): no action, other reasonable courses of action, and mitigation measures. Other reasonable courses of action include alternatives that meet the stated purpose and need and, in this case, are within the available budget. Alternatives are discussed in Chapter 2. Impacts of the No Action Alternative, which would maintain the current operations, are also considered.

1.5.3 Connected, Cumulative, and Similar Actions

The Code of Federal Regulations (40 CFR 1508.25) addresses the scope of analysis and elements to be considered in a Proposed Action. The regulations recognize that separate activities can combine and interact to create impacts that *may be significantly beyond* the effects of individual actions. These actions are considered *cumulative*, and their additive effects must be addressed in the analysis.

Federal regulations also require a combined analysis of *connected* actions. Connected actions are closely related and 1) automatically trigger other actions, 2) could not or would not proceed unless other actions are taken previously or simultaneously, and 3) are interdependent parts of a larger action and depend on the larger action for their justification. The effects of connected actions should be analyzed together. *Similar* actions are those that share a common timing or geography and are evaluated together.

1.5.4 Decision To Be Made

Based on the environmental analysis and consideration of public comments on the Proposed Action, NIH will decide:

- Whether to construct an Integrated Research Facility including a Biosafety Level 4 laboratory at RML;
- Whether upgrades to existing infrastructure included in the Proposed Action would be accomplished; and
- What mitigation and monitoring measures (if any) would be required.

The scope of the Project is confined to issues and potential environmental consequences relevant to the decision. The decision is subject to direction from higher levels. Other agencies with regulatory authority are shown in **Table 1-2**.

The Council on Environmental Quality regulations implementing NEPA require consideration of environmental effects and prescribe mitigation where practical to limit those effects. Reconsideration of other existing NIH/RML decisions or programmatically prescribing mitigation or standards for future NIH/RML activities is beyond the scope of this document.

1.6 PUBLIC SCOPING

A Notice of Intent to prepare an EIS was published in the Federal Register on October 4, 2002. Publication of this notice initiated a 30-day public scoping period that provided for acceptance of comments through November 4, 2002. NIH allowed an additional two weeks for comments, through November 18, 2002. A public scoping meeting was held in Hamilton on October 21, 2002. About 100 people attended that meeting.

NIH published and distributed the draft EIS (DEIS) for the proposed Integrated Research Facility in May 2003. A Notice of Availability was published in the Federal Register on May 23, 2003, which initiated a 60-day public comment period on the DEIS ending on July 21, 2003. A public meeting was held on June 26, 2003, to solicit comments from the public on the DEIS. Approximately 200 people attended the public meeting, at which 31 people provided verbal comments.

Table 1-2.
Regulatory Responsibilities

Authorizing Action	Regulatory Agency
Air Quality Permit	Montana Department of Environmental Quality (MDEQ)
Emergency Response	MDEQ, the Department of Military Affairs, Disaster and Emergency Services Division, and Occupational Safety and Health Administration (OSHA)
National Environmental Policy Act	U.S. Environmental Protection Agency (USEPA), U.S. Department of Health and Human Services (USDHHS), and Council on Environmental Quality
National Historic Preservation Act	State Historic Preservation Office (SHPO)
Infectious and Hazardous Material/Waste Management	MDEQ and OSHA
Transport of Hazardous Material (Wastes)	U.S. Department of Transportation, Federal Aviation Administration, International Air Transportation Association (IATA), MDEQ
Construction Safety	OSHA
Emergency Planning and Community Right-to-Know Act (EPCRA)	USEPA (Region 8)
Safe Drinking Water Act	MDEQ and the City of Hamilton
Radioactive Materials	Nuclear Regulatory Commission

One hundred twenty-two letters, emails, faxes, and comment forms were submitted from 114 separate groups, individuals, and government agencies during the comment period. In response to the comments received by NIH on the DEIS, NIH determined that a supplemental DEIS (SDEIS) would be prepared and submitted to the public for review.

1.6.1 Community Liaison Group Meetings

Regular Community Liaison Group meetings are held at the RML campus to provide a forum for discussion of public issues and concerns about RML. The Community Liaison Group consists of 25 key community stakeholders, including, but not limited to, representatives from local government (mayor of Hamilton and Ravalli County commissioners), advocacy groups, realtors, natural resource agencies, local residents, and emergency response agencies. Members of the Community Liaison Group are encouraged to bring questions and concerns to the meetings for open discussion.

1.6.2 Open House Public Meetings

NIH has held two open house public meetings where citizens expressed their concerns and questions to specialists in biosafety, biosecurity, and disease. One meeting was held before release of the DEIS. One was held after release of the DEIS to take comment on the DEIS. Another public meeting was held January 22, 2004, to take comment on the supplement draft environmental impact statement.

1.6.3 Needs Assessment

As additional public outreach, NIH held informal meetings with people who commented during scoping and with other key community stakeholders in February 2003. The objectives of the "needs assessment" were to provide an opportunity for these people to voice their concerns. Information gathered in the needs assessment was used to develop the Proposed Action, describe the affected environment, determine effects, and help identify reasonably foreseeable actions.

1.6.4 DEIS Comment Period

The comment period on the DEIS began on May 23, 2003, with the Notice of Availability that appeared in the Federal Register. Agencies and people who had submitted written comments at scoping, as well as those who requested it, were provided a copy of the DEIS. The DEIS was posted on the Internet and distributed to local libraries. The comment period ended July 21, 2003. Comments on the DEIS were considered as scoping comments for compilation of the SDEIS.

Comments on the DEIS are summarized and used as described in Section 1.7 below.

1.6.5 SDEIS Comment Period

A public comment period followed the SDEIS. The comment period opened on December 29, 2003, with the notice of availability in the Federal Register. The comment period was 45 days and closed on February 11, 2004. Comments on the SDEIS are included in their entirety in Chapter 5, along with responses.

1.7 IDENTIFICATION OF ISSUES

Five hundred eighty-eight (588) public comments were received during scoping in 103 separate documents (letters, e-mails, phone calls, comment forms). Approximately 10 percent of the comments focused on a need for additional alternatives, six percent identified potential mitigation measures, 60 percent related to issues that could be addressed through effects analyses, and 20 percent were considered to be outside the scope of the EIS. Statements in favor or not in favor of the Project were in 12 comments. Sixteen comments could not be categorized.

Issues identified in the comments were assigned to the following four categories:

- Issue or concern that could develop an alternative;
- Issue or concern that could result in a mitigation measure;
- Issue or concern that could be addressed by effects analysis; and
- Issue or concern outside the scope of the EIS.

A list of issues raised by the public with respect to alternatives, mitigation measures, and the analyses to be completed in the EIS is provided below. There were no unresolved conflicts identified with the Proposed Action that were not addressed by the No Action Alternative.

1.7.1 Alternative Development Comments

Key public scoping comments made concerning alternative development included:

- Requests to construct the Integrated Research Facility in a less populated area, at a more secure facility such as a military installation, or at the NIH campus in Bethesda, MD. These comments are addressed through Alternatives Considered but Eliminated from Detailed Study (Section 2.2.2) on page 2-17.
- Request for more information as to how and why RML was selected overall and given the potential risk to the community through disease outbreaks or increased terrorism. This is addressed in Purpose and Need (Section 1.4), in the Community Safety and Risk section on page 4-5 and in **Appendix B**.
- Comments that a BSL-4 laboratory should not be built, regardless of location. Some people voicing this concern believed that more BSL-4 laboratories would increase the probability of unintentional outbreak through releases, sabotage, or terrorism. This is addressed in the No Action Alternative.

Additional comments on the DEIS related to alternatives considered include:

- Request for additional information about the project, including laboratory equipment used, testing procedures, energy consumption of the Integrated Research Facility, and more details regarding budget and finances. This information is found in the EIS within Sections 2.2 (Proposed Action) and 2.2.1 (No Action Alternative) and **Appendix E** (Standard Operating Procedures of a BSL-4 Laboratory).
- No alternatives besides the No Action Alternative were considered. The rationale for the alternatives considered is presented in Section 2.2.2 of the EIS. Additional information has been included in the Purpose and Need (Section 1.4).
- Information on training opportunities for local emergency providers and requirements for training of laboratory workers has been included in **Appendix E** (Standard Operating Procedures for a BSL-4 Laboratory).
- Animals used for experiments. More information on the care and use of animals has been included in Section 2.1.4.1 beginning on page 2-10.

Additional comments on the SDEIS related to alternatives include:

- Disposal of prions. More information on the disposal of prion-contaminated materials is included in the FEIS.

1.7.2 Mitigation Measures

Potential mitigation measures raised by those individuals providing comments during scoping include:

- Adoption of pollution prevention strategies to avoid or reduce the amount of pollution generated at the facility. Efforts are described in the Disposal of Non-Contaminated Material section on page 2-11 (Section 2.1.5).
- Improving parking for workers and visitors during and after construction of the Integrated Research Facility. This is part of the Reasonably Foreseeable Actions as described on page 4-1.
- Implementation of a car-pooling program for workers commuting to the RML campus. This measure will not be included in the Proposed Action. Parking and traffic are addressed under social issues in Chapter 4. Impacts from added traffic do not require mitigation. Additional analysis of the alternatives on traffic has been included in Section 4.2.1.
- Adopting a policy of studying only those agents associated with emerging diseases at the Integrated Research Facility, and not agents associated with bioterrorism or biodefense. This measure is not included in the Proposed Action because it is in direct conflict with the Purpose and Need (see Section 1.4).
- Creation of a citizen oversight committee to monitor activities at the Integrated Research Facility. This measure will not be included in the Proposed Action because monitoring is done by RML for a number of state and federal agencies and the results are made public. The Community Liaison Group, composed of community members, serves to monitor activities at RML. The RML Institutional Biosafety Committee and the RML Animal Care and Use Committee also have community representatives.
- Improving aesthetics of the campus. This measure is included in the Proposed Action, as well as in Reasonably Foreseeable Actions as described on page 4-1. Aesthetics were considered in the design of the building and landscaping, as well as in the effects analysis.
- Implementation of regular effluent monitoring of air emissions and wastewater discharges are included in Air Quality and Wastewater sections in Chapter 3. The City of Hamilton Department of Public Works conducts wastewater testing (which RML pays for), and RML conducts monitoring of incinerator operating parameters every 60 seconds when the incinerator is operating, as required by their MDEQ Air Quality Permit.
- Use of local contractors for design and construction of the Integrated Research Facility to the greatest extent possible. NIH has hired a national design and engineering firm that specializes in designing and building BSL-4 laboratories. Federal Acquisition Regulations (FAR) require one quarter of participating companies to be small businesses from the region. Local contractors would have the same opportunities as others to work on the project.
- A commitment for direct improvements to the hospital, streets, and emergency response agencies by NIH. This is included in the Reasonably Foreseeable Actions as described on page 4-1.
- Noise and light reduction through more landscaping and buffering. This measure is included in the Proposed Action, as well as Reasonably Foreseeable Actions as described on page 4-1, and was considered in the design of the building as well as in the effects analysis. Information on recently completed noise reduction efforts has been included in Section 3.4.
- Establishment of a process where neighbors could bring concerns to RML during and after construction of the Integrated Research Facility. This measure was included in the Proposed Action. Meetings with neighborhood representatives would be held regularly before, during, and after construction. In addition, the Community Liaison Group, including local residents, will address issues brought to it.
- Purchase of homes at fair market value for anyone that requested it within a few blocks of the Integrated Research Facility because of a

perceived fear of lost value once the Integrated Research Facility is completed. This measure is not included in the Proposed Action because there is no indication that the Proposed Action will have a negative effect on property values (see Chapter 4).

- Publish an emergency plan to be implemented should a laboratory worker be exposed to an agent or in the unlikely release of an agent to the neighborhood. This is already planned, regardless of which alternative is selected, and is included in the description of No Action. RML staff meets periodically with representatives from the FBI, U.S. Attorney's Office, and other local law enforcement to share information and strengthen communication among these groups. RML is a member of the Montana Anti-Terrorism Task Force, the Ravalli County Local Emergency Planning Committee, and Ravalli County Terrorism Preparedness Task Force and will participate in the Ravalli County Pre-Mitigation Plan authorized under the Disaster Mitigation Act of 2000. Emergency BSL-4 procedures are outlined in **Appendix E**, Part 4 of the Standard Operating Procedures (pp E-23 to E-27).

Additional mitigation measures were suggested in comments on the DEIS. They are:

- Include in the federal budget all necessary funds to replace or repair inadequate water mains, pipes/sewer lines, and roads in the city of Hamilton. This measure will not be included in the EIS because these are the responsibility of the city. RML pays for these services as well as their share of upgrades through utility bills.
- Commit to posting a bond in an amount that would cover the expenses of a worst-case scenario where an infectious agent is released to the community. NIH is prohibited by statute from agreeing to post such a bond, but any claims for personal injuries and property damage arising from the negligent acts or omissions of a federal employee may be filed with the United States in accordance with the Federal Tort Claims Act, 28 U.S.C 2671-2680.
- Direct filtered airflow discharges from BSL-4 lab to incineration or autoclave system and monitor temperatures and pH levels of biowaste cookers and digesters. This measure was not included because HEPA filtration of air and sterilization of waste leaving the containment zones undergo several stages of purification before discharge. At the time of release, by-products have already undergone destruction under extreme heat; therefore no additional assurances through incineration or autoclaving are needed. Additional information on the HEPA filters and their maintenance are included under Air Treatment in Section 2.1.3.

There were no additional mitigation measures identified in the comments on the SDEIS.

1.7.3 Effects Analysis Comments

The bulk of the public comments are addressed in the DEIS through a detailed description of the Proposed Action and evaluation of direct, indirect, and cumulative impacts and operations. Issues addressed in the EIS include:

- Short- and long-term impacts associated with parking, noise, lighting, visual aesthetics, and increased traffic in the neighborhood surrounding the RML. This information is included in Chapters 2 and 4 of the EIS. For the SDEIS, additional information on the construction noise and the cumulative effects analysis was clarified. New information was obtained on the current site conditions, which is also included in Chapter 3.
- Impacts on the underlying aquifer from increased water usage. This topic was included in the DEIS in Section 4.8. Additional information was included in Water Supply (Section 4.8) of the SDEIS. This information has been clarified for the FEIS.
- Impacts on the City of Hamilton water and wastewater systems. This topic was included in the DEIS in Section 4.8. Additional information has been included in the Water Supply (Section 4.8).
- Impacts on community infrastructure such as schools, roads, and emergency response agencies. Information was included in Section 4.2 of the DEIS. Additional information on the effects on emergency providers has been included in subsequent EIS documents.
- Increased use and disposal of hazardous chemicals by the Integrated Research Facility.

Information on the use and disposal of hazardous waste was included in the DEIS in Section 2.1.3. Additional information on past use and existing permitted levels has been included in Section 2.1.5 and 2.2.1.2.

- Potential increased threat of outbreak of agents through transport, internal sabotage, inadvertent releases, and outside terrorism. Community safety was addressed in the DEIS. Additional information on the past safety record of biocontainment facilities worldwide is included in the EIS in **Appendix D** – Review of Biocontainment Laboratory Safety Record.
- Cultural and historical impacts. This assessment was included in the DEIS in Section 4.6. Since the DEIS was completed, the Montana State Historic Preservation Office has determined that the project would have no adverse effect on the RML historic district. This information has been included in the SDEIS and FEIS.
- Full description of agents to be studied at the lab. This information was included in **Appendix B**.
- Discussion of the security of the facility, including worker clearances. This information is discussed in Section 2.1 and **Appendix C**. In addition, **Appendix E** – Standard Operating Procedures for a BSL-4, is included in the SDEIS (and FEIS) with additional information on security measures.
- Impacts on air quality associated with increased use of the incinerator. Information was included in Section 4.7.1 of the DEIS. Additional information on air quality has been included in Sections 3.7 and 4.7.
- Social and economic impacts of the Integrated Research Facility such as population growth, potential decrease in property values, employment, and school enrollment. This information was included in Section 4.2 of the DEIS. Additional information on the effects of BSL-4 laboratories on housing prices has been included in Section 4.2.
- Potential damage to the Integrated Research Facility from an earthquake or flood. Construction methods to prevent damage from earthquakes were included in Section 2.1 of the EIS. Flood damage would be avoided by not constructing the facility in the 100-year floodplain, which is addressed in Chapter 3 (Section 3.9.3).
- Description of previous releases of biological agents at RML. This information is included in the new **Appendix D**.
- Discussion of any new or expanded permits that would be required for the Integrated Research Facility. This information was included in Chapter 3 of the DEIS and subsequent EIS documents.

Additional comments made on the DEIS on effects analysis include:

- Impacts on wetlands, wildlife, and threatened and endangered species. These resources were addressed in the DEIS as Resources Not Affected (Section 3.9). Rationale for why these resources would not be affected is included in that section.

There were no new analysis issues identified in comments on the SDEIS.

1.7.4 Issue or Concern Outside the Scope of the EIS

The following comments made during the initial scoping period were determined to be outside the scope of the analysis because the information was not relevant to the decision, not affected by the proposed action, not within the analysis area, or already decided by law or policy:

- Statements of support or in opposition to the project. These comments are outside of the scope of the analysis in the EIS, but they will be considered during decision-making and addressed in the Record of Decision.
- Delays caused by the NEPA process.
- Decision-making authority.
- Research of cancer incidents in the neighborhood and results of toxic dumping.
- A programmatic EIS should be done for the proposed upgrade at RML as well as those upgrades or new facilities proposed across the country. Locations and plans for current and future BSL-4 laboratories nationwide should be disclosed.

- How long would it take for smallpox to spread through a town such as Hamilton?
- Redirect the money for this project to AIDS research or universal health care.
- NEPA coverage for previous projects at RML was inadequate.
- Provide detailed project budget in the EIS.
- Please list all violations in RML's history. What were they? When did they occur? How and when were they cleaned up or resolved?
- Provide a detailed budget for the project disclosed in the EIS.
- Will public have opportunity to oversee the building/engineering process? Commentors would like for public to be involved in the certification process, specifically the testing to meet BSL-4 standards and codes, and for these documents to be made public.

An additional comment was made on the DEIS that was considered outside the scope of the EIS:

- Effects downwind on our Canadian neighbors.

There were no additional comments on the SDEIS that were considered outside the scope.

1.7.5 Other Comments on the EIS

A few comments on the EIS were received that did not fit into the categories for scoping comments, but information has been included to address them. They are:

- No one who prepared the DEIS appear to have the experience in safety or microbiology to assure the public that the DEIS has the scientific integrity required by NEPA. In response to this comment, the List of Preparers has been expanded to include NIH personnel who were integral in the preparation of the DEIS and SDEIS and their qualifications.
- Construction began for proposed alternative, which has irrevocably committed resources. To clarify, no construction on the Integrated Research Facility has occurred. Some money has been spent by NIH to design the facility, which is needed to complete the NEPA analysis.